#### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	<ul> <li>) MDL No.1456</li> <li>) Master File No. 01-CV-12257-PBS</li> <li>) Subcategory No. 06-CV-11337-PBS</li> </ul>
	) Judge Patti B. Saris
THIS DOCUMENT RELATES TO:	)
U.S. of America ex rel. Ven-A-Care	) Magistrate Judge Marianne B. Bowler
of the Florida Keys, Inc., et al. v.	)
Boehringer Ingelheim Corporation, et al.,	) Leave to file granted on December 17, 2009
Civil Action No. 07-10248-PBS	)

# THE ROXANE DEFENDANTS' SUR-REPLY MEMORANDUM IN FURTHER OPPOSITION TO PLAINTIFF'S MOTION TO CONSOLIDATE CASES FOR TRIAL

Dated: December 17, 2009

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Roxane Laboratories, Inc.

The DOJ's reply arguments make clear that the DOJ has little interest in whether consolidation denies the Roxane Defendants their right to a fair and impartial trial. The DOJ also shows little regard for its burden of establishing that the benefits of consolidation trump the risk of any detriment that may result. To the DOJ, the analysis of the consolidation question should only focus on how Defendants' AWPs for a single drug impacted Medicare. The DOJ is wrong.

- First, the DOJ asserts that the parties could save time and resources because in a consolidated trial the differences between the companies, their scienter, their drugs, and the markets in which those drugs compete are largely irrelevant. (See Dkt. # 6660, U.S. Reply in Supp. of Mot. to Consol. ("US Reply") 2-3) But the law of this Court holds that liability in AWP cases must be established "drug by drug," Massachusetts v. Mylan Labs., 608 F. Supp. 2d 127, 155 (D. Mass. 2008), "company by company, . . . NDC by NDC, and quarter by quarter." Tr. of Status Conf. 20 (D. Mass. July 17, 2007) (Ex. A).
- Second, although the DOJ frames the risk that Defendants would face substantial jury confusion and prejudice in a consolidated trial as "speculative," (see US Reply 4), these concerns have been borne out of the experience of this Court and other state courts with experience trying AWP cases. (See Dkt. # 6635, Dey Opp'n to US Mot. to Consol. ("Dey Opp'n") 7-8 (citing MDL Tr. at 11, 28-29 (D. Mass. Aug. 27, 2007); Wisconsin v. Abbott Labs., No. 04-CV-1709, 3/10/09 Mot. Hr'g, 13))
- *Third*, the DOJ's overreaching (and unpled) "combined impact" theory is wrong as a matter of law and fact and finds no support in joint and several liability principles. It therefore cannot serve as a predicate for consolidation. (*See* Dkt. # 6585, US Mem. in Supp. of Consol. ("US Mem.") 14; Tr. of 10/20/09 SJ Hr'g 24-25)
- *Last*, the DOJ's proposed trial phasing misses the mark. Having these separate cases proceed in a consolidated Medicare trial and then in a Medicaid trial actually *decreases* efficiency—by duplicating the only portion of the case that is *at all* suited for consolidation. It also fails to alleviate the risk of the prejudice highlighted by the Defendants.

In short, a consolidated trial does not lessen the DOJ's co-extensive burdens of production and persuasion but it does deprive the Roxane Defendants of a fair and impartial trial. The stakes are too high here to sacrifice fundamental fairness at a tenuous altar of efficiency. *See Malcolm v. Nat'l Gypsum Co.*, 995 F. 2d 346, 350 (2d Cir. 1993). Accordingly, the Court should deny the DOJ's motion, or, in the alternative, accept Roxane's proposal for a partially consolidated trial.

## I. CONSOLIDATION WOULD CONFUSE THE JURY AND CAUSE SEVERE PREJUDICE TO DEFENDANTS.

To downplay the confusion and prejudice a consolidated trial poses, the DOJ characterizes

these risks as "speculative." But these risks are far from speculative—rather, they are the cumulative experience of AWP courts after presiding over AWP trials. Several courts, in addition to this Court, have recognized the real danger of confusion and prejudice, as described in Dey's Sur-Reply, which is adopted and incorporated herein. (*See also*, Dey Opp'n 7-8) The DOJ's arguments also fail for the following reasons:

First, the DOJ's attempt to minimize the distinctions among the various drugs ignores the basic law of the False Claims Act. The DOJ wrongly argues that consolidation will increase efficiency because the DOJ can prove its False Claims Act count with evidence of "certain" of the Subject Drugs. (US Reply 2-3) But issues of liability "will have to be resolved drug by drug" and company by company. Mylan Labs., 608 F. Supp. 2d at 155; Dkt. # 6629, Roxane Opp'n to US Mot. to Consol. ("Rox. Opp'n) 15-16; Dkt. # 6748, Ex. 1 to Dey Mot. for Lv. to File Sur-Reply ("Dey Sur-Reply") 2. This burden necessarily requires distinct evidentiary presentations for each drug, including, but not limited to, the markets in which they competed; the sales, marketing, and pricing activities of each Defendant with respect to each drug; and the available pricing information in the marketplace to federal and state officials. Indeed, although it is true that each case will involve similar evidence regarding certain reimbursement formulae, the DOJ fails to acknowledge that even with such similarities, a drug-by-drug analysis will still be necessary—and across all fifty Medicaid programs too—because different drugs were reimbursed on different bases at different times (e.g., different MACs).\(^1\)

Second, the authorities on which the DOJ relies do not support its request for consolidation.

<sup>&</sup>lt;sup>1</sup> The DOJ's assertion of alter ego and direct liability claims against BIC and BIPI further illustrates just how complex this individualized inquiry will be, as each element of the claims at issue will be examined not only on a drug-by-drug basis, but also with respect to the conduct of BIC, BIPI, and Roxane. Because the DOJ's claims concern NDCs that do not belong to either BIC or BIPI, jurors will have to engage in a careful, detailed, and individualized determination, on a drug-by-drug basis, of whether BIC and BIPI each separately had the requisite intent and involvement in establishing AWPs for each *Roxane* drug.

The DOJ's primary reliance on securities class action decisions is misplaced. Courts have repeatedly held that "consolidation is particularly appropriate in the context of securities class actions" where complaints are based on the same public statements and reports of the defendant group. Glauser v. EVCI Career Coll. Hold'g Corp., 236 F.R.D. 184, 186 (S.D.N.Y. 2006). No such presumption exists for False Claims Act cases. Moreover, in most of the decisions cited by the DOJ—and unlike in this case—none of the parties actually opposed consolidation.<sup>2</sup> In contrast, Defendants here not only oppose consolidation, but also have demonstrated the inevitable jury confusion and prejudice that they would confront in a consolidated trial. Here, the statements and conduct that form the bases of the case pled against unrelated actors Dey and Roxane are not the same and do not even relate to the same time or NDCs. For the very reasons cited by the DOJ in its discussion of Henderson v. AT&T Corp.—namely, that that case involved "highly individualized" claims and parties working "on separate teams, in separate offices calling on different customers"—consolidation is not appropriate. (See US Reply 4 (citing 918 F. Supp. 1059 (S.D. Tex. 1996)))<sup>3</sup>

# II. NEITHER THE ASSERTED "RISK OF INCONSISTENT JUDGMENTS" NOR THE DOJ'S UNTENABLE DAMAGES THEORY JUSTIFIES CONSOLIDATION.

The DOJ's "inconsistent judgment" and so-called "combined impact" theories have no application to this case. *First*, there is no risk of "inconsistent" results in trying these separate cases before separate juries. These are, after all, different companies, selling and marketing different

<sup>&</sup>lt;sup>2</sup> See MicroStrategy, Inc. Sec. Litig., 110 F.Supp.2d 427, 431-32 (E.D. Va. 2000) ("[I]t is apparent that no party will suffer prejudice from consolidation, a fact confirmed by the complete absence of any opposition"); Bowman v. Legato Sys., Inc., 195 F.R.D. 655, 656-57 (N.D. Cal. 2000) (similar); Sofran v. LaBranche & Co., 220 F.RD. 398 (S.D.N.Y. 2004) (no apparent opposition). In the only other decision the DOJ cites for this argument, In re Bear Sterns Cos., "none of the parties object[ed] to the consolidation of the majority of the Securities Actions," and, with respect to the few that did object, the claims in the cases were identical, as well as the Defendants' statements forming the bases for those claims. 2009 WL 50132, at \*6 (S.D.N.Y. Jan. 5, 2009).

<sup>&</sup>lt;sup>3</sup> Moreover, in an attempt to draw the Court's attention away from the very real danger of confusion and prejudice, the DOJ argues—with little explanation—that jury instructions are a panacea for the ills of a consolidated trial. (US Reply 3-4) But the only support for that proposition is no support at all. The DOJ's reply brief misleadingly cites a decision that, on rehearing *en banc*, concluded that consolidation *did* in fact cause prejudice, which resulted in reversible error. *Arnold v. E. Air Lines, Inc.*, 712 F.2d 899, 906-07 (4th Cir. 1983).

drugs in different ways, and the claims alleged may not be of identical merit. In its opposition memorandum, the Roxane Defendants distinguished the DOJ's only authority for its argument, *Int'l Paving Sys. v. Van-Tulco, Inc.*, 806 F. Supp. 17 (E.D.N.Y. 1992), which involved the consolidation of breach-of-contract cases concerning the claims of a general contractor and its sub-contractor. (*See* Rox. Opp'n 17, n.14) The DOJ does not respond to the Roxane Defendants' argument. In any event, the First Circuit has held that the risk of inconsistent judgment does *not* justify a consolidated trial where irreparable prejudice to the defendants will result. *See Seguro De Servicio De Salud De Puerto Rico v. McAuto Sys. Group, Inc.*, 878 F.2d 5, 9 (1st Cir. 1989) (holding that court abused discretion in consolidating cases where possibility of irreparable harm existed). Whatever the merit of the DOJ's "inconsistent" judgment theory—and there is none—Defendants will inevitably suffer irreparable harm in a consolidated trial.

Second, although the DOJ argues that its "combined impact theory" finds support in the common law, none of its allegations or cited authority supports its argument. (See US Reply 6) At the outset, the DOJ makes no allegation of conspiracy, collusion, or concerted action between Defendants in these separate cases and the DOJ alleges no facts (or otherwise gives notice) supporting its suggestion of joint and several liability. (See Rox. Opp'n 5 (citing DOJ complaints); Dey Opp'n 2, 11, 17 (showing no allegations of collusion or conspiracy))<sup>4</sup> Indeed, the principle of joint and several liability does not apply because, as this Court has held, this theory of liability requires that an injury caused by multiple defendants be indivisible. See In re AWP Litig., 491 F.

<sup>&</sup>lt;sup>4</sup> Similarly, the DOJ's authority is inapposite, both because none of these decisions involved turned on a contested issue of joint and several liability and each decision involved defendants that had contractual relationships or interacted with the same injury-causing item, neither of which is at issue here. (US Reply 8 (citing *Shepard v. Gen. Motors Corp.*, 423 F.2d 406 (1st Cir. 1970) (suggesting in dicta that defendants were joint tort-feasors where defendants respectively manufactured and operated the same car that injured plaintiff); *Hawley v. Am. Eagle Sailing, Inc.*, 2007 WL 3012133 (M.D. Fla. 2007) (finding joint and several liability where defendants all allegedly falsely represented that they would guarantee the same note, but where *no defendant filed a response to the motion*); *Agere Sys., Inc. v. Advanced Envt'l. Tech. Corp.*, 552 F. Supp. 2d 515 (E.D. Pa. 2008) (holding that parties were *not* joint tort-feasors))

Supp. 2d 20, 100-01 (D. Mass. 2007) (citation omitted). An injury is divisible where the harm, "while not so clearly marked out as severable into distinct parts, [is] still capable of division upon a reasonable and rational basis." *Id.* (citing Rest. (2d) Torts § 433A cmt. d). The DOJ has not shown that the alleged injury is indivisible. Quite the contrary: the *DOJ's own damages expert* divided the alleged damages and apportioned them between Defendants. (*See* Dkt. #6207, Tab 166, 1-4, Tbl. 37) Additionally, indivisibility requires that "each relevant person caused the entire injury." *In re AWP Litig.*, 491 F. Supp. 2d at 101 (quotation omitted). Yet the DOJ admits that the Roxane Defendants did not cause the entire injury claimed. (*See* US Mem. 14-15) The principle of joint and several liability thus has no application here and cannot serve as a predicate for consolidation.<sup>5</sup>

## III. THE DOJ'S PROPOSED TRIAL PHASES WILL NOT PROMOTE EFFICIENCY OR REDUCE PREJUDICE.

If the Court is inclined to consolidate a portion of the Dey and Roxane cases, it should use Roxane's proposal for a limited common presentation of government-specific evidence. (*See* Rox. Opp'n 18-19) The purported savings from the DOJ's proposal for a "Medicare-only" trial is a false economy. The DOJ's proposal for Medicare- and Medicaid-only trials would not save time or resources; rather, the proposal would *increase* the amount of time and resources devoted to trial. (Dey Sur-Reply 3-4) More importantly, because both proposed phases would still pertain to trying the Dey and Roxane Defendants before a single jury, the proposal in no way ameliorates the grave risk of prejudice that Defendants have highlighted. In contrast to the DOJ's proposal, which neither improves efficiency nor eliminates prejudice, Roxane's proposal optimizes both factors.

#### **CONCLUSION**

For all the foregoing reasons, and for the reasons stated in Roxane's memorandum in opposition, the Court should deny the DOJ's Motion to Consolidate Cases For Trial.

<sup>&</sup>lt;sup>5</sup> The Roxane Defendants do not intend to address in this sur-reply all of the legal deficiencies of the DOJ's "combined impact" theory of liability, and will challenge further the DOJ's untenable theory at a later date.

Dated: December 17, 2009 Respectfully submitted,

/s/ John W. Reale

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### **CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on December 17, 2009, a copy to LexisNexis File and Serve for posting and notification to all parties.

/s/ John W. Reale
John W. Reale